JC03 Rec'd PCT/PTO 1 9 0CT 2009

| 000FORN REV. 2/0 | и РТО-1390 1Т | U.S. DEPA | CUSTOMER NO. 22,852 | | | | | | | |
|--|------------------|---|---|-----------|--|--|--|--|--|--|
| 7 | [RANS] | MITTA | ATTORNEY'S DOCKET NUMBER | | | | | | | |
| | DESI | [GNAT] | 07680.0023-00000 | | | | | | | |
| | CON | CERNI | NG A | FILIN | IG UNDER 35 U.S.C. 371 | U.S. APPLICATION NO. (If known, see 37CFR1.5) | | | | |
| | | | | | | Not Mt 0 55 5 3 5 9 5 | | | | |
| INTER | NATIONA | L APPLIC | CATION | NO. | INTERNATIONAL FILING DATE | PRIORITY DATE CLAIMED | | | | |
| D C77/7 | 100004/01 | | | | | | | | | |
| PC1/U | JS2004/013 | 30// | | | 30 April 2004 | 30 April 2003 | | | | |
| TITLE OF INVENTION TGF-BETA ANTAGONISTS COMBINED WITH RENIN-ANGIOTENSIN-ALDOSTERON-SYSTEM ANTAGONISTS FOR TREATING RENAL INSUFFICIENCY | | | | | | | | | | |
| APPLICANT(S) FOR DO/EO/US LEDBETTER et al. | | | | | | | | | | |
| Applicant(s) herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | | | | | | | | | |
| 1. | \boxtimes | This is a | FIRST s | ubmissio | on of items concerning a filing under 35 U.S.C 3 | 71. | | | | |
| 2. | | | This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. | | | | | | | |
| 3. | | | This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. | | | | | | | |
| 4. | | The US 1 | nas been | elected b | y the expiration of 19 months from the priority | date (Article 31). | | | | |
| 5. | \boxtimes | A copy o | f the Inte | | l Application as filed (35 U.S.C. 371 (c)(2)). | | | | | |
| | | a. | \boxtimes | | ched hereto (required only if not communicated | by the International Bureau). | | | | |
| | | b. | \boxtimes | | en communicated by the International Bureau. | | | | | |
| | _ | c. | | | required, as the application was filed with the U | | | | | |
| 6. | | An Engli | | - | lation of the International Application as filed (3 | 35 U.S.C. 371 (c)(2)). | | | | |
| | | a. | | | ched hereto. | | | | | |
| | _ | b. | | | en previously submitted under 35 U.S.C. 154 (d | | | | | |
| 7. | \boxtimes | Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)). | | | | | | | | |
| | | a. • | | | ached hereto (required only if not communicated | by the International Bureau). | | | | |
| | | b. | | | een communicated by the International Bureau. | 1 1 1 NOT a mind | | | | |
| | | C. | | • | ot been made; however, the time limit for making | ig such amendments has NOT expired. | | | | |
| • | | d. | ⊠ | | ot been made and will not be made. | CT A 4:-1- 10 (25 H C C 271 (-)(2)) | | | | |
| 8. | ⊔ ⊠ | An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)). | | | | | | | | |
| 9. 10. | | | An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under PCT | | | | | | | |
| ••• | _ | Article 3 | | | | , | | | | |
| Items 1 | | | | | r information included: | | | | | |
| 11. | ⊠ | Information Disclosure Statement under 37 CFR 1.97 and 1.98 | | | | | | | | |
| 12. | | An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. | | | | | | | | |
| 13. | | A FIRST preliminary amendment. | | | | | | | | |
| 14. | | A SECOND or SUBSEQUENT preliminary amendment. | | | | | | | | |
| 15. | | A Substitute specification. | | | | | | | | |
| 16. | | A change of power of attorney and/or address letter. | | | | | | | | |
| 17. | | A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825. | | | | | | | | |
| 18. | | A second copy of the published international application under 35 U.S.C. 154 (d)(4). | | | | | | | | |
| 19. | | | | | | | | | | |
| | | a. | ⊠ M | | PCT/IB/304, mailed July 2, 2004 from the Intern | | | | | |
| | | b. | ⊠ ⊠ | | PCT/IB/308, First Notice mailed December 2, 2 | | | | | |
| | | c. | \boxtimes | | PCT/IB/308, Second and Supplementary Notice ational Bureau | mailed September 1, 2005 from the | | | | |

JC12 Rec'd PCT/PTC 1 9 OCT 2005

| U.S. APPLICATION NO. (If known, see 37CFR 1.5) Not Yet Assigned 1 0 5 5 3 5 9 RCT/US2004/013677 | | | | | | | ATTORNEY'S DOCKET NUMBER 07680.0023-00000 | | |
|---|--|---------------|--|---------|----------|------------------------|---|--|--|
| 21. \(\sime\) The follo | | Applicant Use | Office Use Only | | | | | | |
| BASIC NATION | \$300.00 | \$300.00 | | | | | | | |
| National Stage Sea | \$500.00 | \$500.00 | | | | | | | |
| _ | | \$200.00 | | | | | | | |
| National Stage Examination Fee\$200.00 | | | | | | | | | |
| ENTER APPROPRIATE BASIC FEE AMOUNT = $\$1,000.00$ | | | | | | | | | |
| Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | | | | | |
| Total Sheets | | | Number of additional 50 or fraction Rate thereof (rounded up to a whole number | | Rate | | | | |
| - 100 = | | /50= | | | x 250.00 | \$N/A | | | |
| | | | or declaration later than (37 CFR 1.492 (e)). | □ 20 | □ 30 | \$ | | | |
| CLAIMS | | BER FILED | NUMBER EXTRA | RAT | <u> </u> | | + - | | |
| Total Claims | 44 | - 20 = | 24 | x \$50. | | \$1,200.00 | + | | |
| Independent Claims | 3 | -3 = | 0 | x \$200 | .00 | \$0.00 | | | |
| MULTIPLE DEPEN | MULTIPLE DEPENDENT CLAIM(S) (if applicable) +\$360.00 | | | | | | | | |
| | MULTIPLE DEPENDENT CLAIM(S) (if applicable) +\$360.00 \$360.00 TOTAL OF THE ABOVE CALCULATIONS = \$2,560.00 | | | | | | | | |
| ☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by \$ 1/2. | | | | | | | | | |
| | \$2,560.00 | | | | | | | | |
| Processing fee of \$130.00 for furnishing the English translation later than 20 30 \$0.00 months from the earliest priority date (37 CFR 1.492(f)). | | | | | | | | | |
| TOTAL NATIONAL FEE = \$2,560.00 | | | | | | | | | |
| | NCLOSED = | \$ 0.00 | | | | | | | |
| | | | | | | Amount to be refunded: | \$ | | |
| | | | | | | charged: | \$ | | |
| a Please charge Deposit Account No. <u>06-0916</u> in the amount of \$2,560.00 to cover the above fees. A duplicate copy of this sheet is enclosed. | | | | | | | | | |
| b. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>06-0916.</u> A duplicate copy of this sheet is enclosed. | | | | | | | | | |
| SEND ALL CORRESPONDENCE TO: | | | | | | | | | |
| Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. | | | | | | | | | |
| 901 New York Avenue, NW Leslie A. McDonell, Reg. No. 34,872 Workington, D.C. 20001, 4413 | | | | | | | | | |
| Washington, D.C. 20001-4413 | | | | | | | | | |
| DATED: October 19, 2005 | | | | | | | | | |
| CERTIFICATE UNDER 37 CFR § 1.10 OF MAILING BY "EXPRESS MAIL" | | | | | | | | | |
| I hereby certify that this correspondence is being deposited with the United States Postal Services "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on October 19, 2005 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Express Mail Label No. EV 411565485 US | | | | | | | | | |

Michelle Manning

10/553595 JC12 Rec'd PCT/PTC 1 9 OCT 2005

CERTIFICATE UNDER 37 CFR § 1.10 OF MAILING BY "EXPRESS MAIL"

| EV 411565485 US | October 19, 2005 |
|--------------------------------|------------------|
| USPS Express Mail Label Number | Date of Deposit |

1)

I hereby certify that this correspondence is being deposited with the United States Postal Services "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Michelle C. Manning